



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

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## CERTIFICATE OF ANALYSIS

Date: 11-10-2017

Product Name	CLEARLENSE CLEANSING SC VH9
Product Code	7516429
Batch Number	FMP 17282 43373
Production Date	09/10/2017
Expiration Date	Exp. 09/10/2019

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear	Slightly Yellow Liquid	Clear Slightly Yellow Liquid
pH (100% 20°C)	JDM001	12.0	13.0	12.9
Specific Gravity (20°C)	JDM004	1.040	1.060	1.052

On behalf of Diversey site Quality Manager	Name :	Agg. Krishna Parhyish
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7516429	Version : 04	Date of issuing : April 27 <sup>th</sup> 2012
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# Wickham Laboratories

Contract Analytical Services

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Telephone: +44(0)1329 226600  
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Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 16 Oct 2017  
**Date Tested:** 24 Oct 2017  
**Date Test Completed:** 15 Nov 2017  
**Purchase Order:** 29787

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0038575/2  
**Test Required:** Sterility by Membrane Filtration Steritest  
**Date Received:** 16/10/2017  
**Test Article:** Cleansinald SC  
**Sample Code:** FMP17282 43373  
**Batch Ref:** 578406  
**Qty Received:** 20 x 25mL Bottles

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in one broth
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in one broth
Growth of Sub-culture in TSB at 20-25°C after 4 - 7 days	MM107/07	No growth in one broth
Growth of Sub-culture in THY at 30-35°C after 4 - 7 days	MM107/08	No growth in one broth
Volume Tested	MM107/05	20 x 25 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM06

### Comments

Corrected C of A to LR 0038575/2 authorised 17/11/17 due to space required in between the sample code.

Approval is provided by Electronic Signature. Their name and position is shown below.

 CBiol MRSB

Date: 20 Nov 2017 13:35:36

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 29-Sep-2017

UK33S11962706-2-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products

EN ISO 9001:2008 Quality Management System

EN ISO 13485:2012 Quality System - Medical Devices

Flexible Medical Packaging Ltd  
Unit 8, White Cross Ind Estate  
Hightown  
Lancaster  
Lancashire LA1 4XS  
UNITED KINGDOM

All in accordance with current Technical Agreement

## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1111497
Customer Reference Number:	P029612
Product Description:	C/SINALD BOTTLES/CAPS/BAGS DV4894 25-40KGS
Validation Reference:	4894
Quantity Received:	11
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO43374, 2PLTS

## Irradiation Data

Date and Time of Irradiation:	29-Sep-2017 04:59
Reference Dose Range kGy:	29.5 - 29.9
Calculated Minimum Dose kGy:	26.9
Calculated Maximum Dose kGy:	32.8

Items irradiated under WO43374, will be used in finished product batch FMP17282 43373

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
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